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(54) Title: RETRACTABLE NEEDLE MEDICAL DEVICE

(54) Titre: DISPOSITIF MÉDICAL A AIGUILLE RÉTRACTABLE

(57) Abstract

A catheter insertion device (10) is provided for inserting an over-the-needle catheter (70). The device (10) includes an insertion needle (30) that is retractable into the housing (20) of the device (10) after use to prevent exposure to the contaminated needle (30). The needle retainer (40) releasably retains the needle (30) in an extended position against the rearward bias of the biasing element (60). The needle retainer (40) engages the hub (72) of the catheter (70) so that when the catheter is removed from the insertion device (10), the needle retainer (40) automatically releases the needle (30). The biasing element (60) then propels the needle rearwards into the housing (20) of the device. Further, a device for inserting a guide wire into a patient is also provided along with methods of inserting the guide wire.

(57) Abrégé

L'invention se rapporte à un dispositif (10) conçu pour permettre l'introduction d'un cathéter (70) sur aiguille. Ledit dispositif (10) comporte une aiguille d'insertion (30) qui peut être escamotée à l'intérieur du logement (20) dudit dispositif (10) après utilisation pour éviter l'exposition à l'aiguille contaminée (30). L'organe de retenue (40) de l'aiguille retient l'aiguille de manière libérable (30) dans une position déployée à l'encontre de la sollicitation exercée vers l'arrière par un élément de sollicitation (60). Ledit organe de retenue (40) entre en contact avec l'embout (72) du cathéter (70) de sorte que lorsque le cathéter est retiré du dispositif d'introduction (10), ce dispositif de retenue (40) libère automatiquement l'aiguille (30). L'élément de sollicitation (60) propulse alors l'aiguille vers l'arrière de façon à la faire rentrer dans le logement (20) du dispositif. L'invention se rapporte en outre à un dispositif permettant d'introduire un fil-guide dans un patient ainsi qu'à des procédés d'introduction dudit fil-guide.

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(57) Abstract <p>A catheter insertion device (10) is provided for inserting an over-the-needle catheter (70). The device (10) includes an insertion needle (30) that is retractable into the housing (20) of the device (10) after use to prevent exposure to the contaminated needle (30). The needle retainer (40) releasably retains the needle (30) in an extended position against the rearward bias of the biasing element (60). The needle retainer (40) engages the hub (72) of the catheter (70) so that when the catheter is removed from the insertion device (10), the needle retainer (40) automatically releases the needle (30). The biasing element (60) then propels the needle rearwards into the housing (20) of the device. Further, a device for inserting a guide wire into a patient is also provided along with methods of inserting the guide wire.</p>			

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Description

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Retractable Needle Medical Device**Field of Invention**

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5 The present invention relates to needle-bearing medical devices used, for example, to insert catheters or guide wires into blood vessels of patients. More specifically, the invention relates to such a device having a retractable needle feature for rendering the device non-reusable and safely disposable.

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10 **Background**

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Various types of medical devices employed a needle for piercing the skin of a patient for diagnostic or therapeutic purposes. One such device is an intravenous catheter insertion device for positioning a needle mounted catheter into a patient's blood vessel. Another such device is the device for introducing a guidewire into a patient. The guidewire is then used to guide a catheter into the patient. Once the guidewire or catheter is properly positioned, the catheter insertion device is withdrawn leaving the guidewire or catheter in place in the blood vessel. Handling of such medical devices after the needle is withdrawn from the patient can result in transmission of various pathogens, most notably human immune virus (HIV), due to inadvertent needle stick to medical personnel.

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Since the mid-1980s, concern over the risk of accidental needle stick injuries has spawned a number of design approaches for safety needle devices. Such devices can be broadly categorized as either sliding sheath needle devices, wherein a physical barrier is positioned over the needle tip after use or as devices with needle retraction, wherein the exposed portion of the needle is retracted into the device after use. The

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5 latter category of needle retraction devices can be
further subdivided into manual and semiautomatic
retraction devices. Manual retraction devices, as
10 exemplified by U.S. Patent Nos. 4,026,287 to Haller,
5 4,592,744, to Jagger, 4,808,169 to Haber and 5,067,490 to
Haber, require the user to pull or slide a needle-
connected mechanism rearwardly to retract the needle into
15 the device. In semiautomatic needle retraction devices,
a biasing member, such as a spring, may be employed to
10 push or pull the needle into the device in response to
activation by the user of a release mechanism. Such
20 devices are exemplified by U.S. patent numbers 4,813,426
to Haber et al. and 5,125,414 to Dysarz.

 U.S. Patent No. 4,747,831 of Kulli and U.S. Patent
15 No. 4,900,307 of Kulli show respective catheter insertion
25 devices and syringes with semiautomatic needle
retraction. The retraction mechanism shown in the last-
mentioned two patents are disclosed to be actuable by the
30 user upon depression of a release button after the
20 catheter is removed from the insertion device or the
needle is removed from the patient.

 The prior art semiautomatic devices require manual
actuation by the operator. In many situations, such as
35 an emergency situation, the operator is distracted or
25 rushed so that the manual step necessary to effectuate
retraction is not performed, either intentionally or
40 unintentionally. In such instances, the used needle
remains exposed, creating a risk of an inadvertent needle
stick. Therefore, it would be desirable to provide an
30 automatic needle retraction mechanism in which needle
retraction is effectuated by normal operation of
45 inserting the catheter into the patient, without the need
to perform a separate manual step. It is further
desirable to provide a device with a limited number of
35 components so that the device can be produced cost

effectively.

Summary of Invention

With the foregoing in mind, the present invention provides a medical device having a hollow housing and a catheter mounted on the housing. The device includes a needle operable between an extended position extending forwardly from the housing and a retracted position in which the needle is enclosed in the housing. A biasing element biases the needle toward the retracted position. A needle retainer is fixedly connected with the needle. The needle retainer releasably retains the needle in the extended position against the bias on the biasing element. The needle retainer preferably comprises an elongated arm having a follower portion engaging the catheter. Upon removal of the catheter from the housing, the catheter disengages the follower portion, thereby allowing the needle retainer to release the needle. The biasing element then propels the catheter rearwardly into the housing.

The present invention also provides a medical device having a hollow housing and a needle for inserting a guidewire. The device includes a needle operable between an extended position extending forwardly from the housing and a retracted position in which the needle is enclosed within the housing. A biasing element biases the needle toward the retracted position. The device includes a needle retainer operable between a first position in which the needle retainer releasably engages the needle against the rearward bias of the biasing element, and a second position in which the needle retainer releases the needle allowing the biasing element to displace the needle into the retracted position. The guidewire engages the needle retainer to impede the needle retainer from displacing into the released position. After the

5 guidewire is threaded into the patient, the needle
retainer is displaced into the released position, and the
10 biasing element propels the needle rearwardly into the
housing.

15 The present invention also provides a method for
inserting a medical apparatus carried by a needle, such
as an intravenous catheter or guidewire. The method
includes the step of providing an insertion device having
20 a housing, a needle and a needle retainer for releasably
retaining the needle so that the needle projects
forwardly from the housing. The medical apparatus is
inserted into the patient via the needle. The operator
selectively manually engages the needle retainer to
25 impede retraction of the needle. The operator then
releases the selective manual engagement with the needle
retainer to release the needle. The needle is then
retracted into the housing.

Description of Drawings

30 The foregoing summary as well as the following
detailed description of the preferred embodiments of the
present invention will be better understood when read in
conjunction with the appended drawings, in which:

35 Fig. 1 is a perspective view of a catheter insertion
25 device having a retractable needle;

Fig. 2 is a cross-sectional view of the device shown
in Fig. 1;

40 Fig. 3 is a cross-sectional view of the device shown
in Fig. 2, illustrating the device with the catheter
30 removed prior to retraction of the needle;

45 Fig. 4 is a cross-sectional view of the device shown
in Fig. 2, illustrating the device after retraction of
the needle;

50 Fig. 5 is a cross-sectional view of an alternate
35 embodiment of a catheter insertion device having a

5 retractable needle;

Fig. 6 is a cross-sectional view of the device shown in Fig. 5, illustrating the device with the catheter removed prior to retraction of the needle;

10 5 Fig. 7 is a cross-sectional view of the device shown in Fig. 5, illustrating the device after retraction of the needle;

15 Fig. 8 is a side elevational view of a retractable needle device for introducing a guide wire into a patient;

20 Fig. 9 is an enlarged fragmentary sectional view of the guide wire introduction device illustrated in Fig. 8;

Fig. 10 is a side view of the guide wire introduction device illustrated in Fig. 8, illustrating the needle in a retracted position;

25 Fig. 11 is a side elevational view of a second embodiment of a retractable needle device for introducing a guide wire into a patient;

30 20 Fig. 12 is a side view of the guide wire introduction device illustrated in Fig. 11, illustrating the needle in a retracted position;

35 Fig. 13 is a side elevational view of a catheter insertion device with a retractable needle according to the present invention;

25 Fig. 14 is a bottom plan view of the catheter insertion device illustrated in Fig. 13;

40 Fig. 15 is a sectional view of the catheter insertion device illustrated in Fig. 13;

30 Fig. 16 is a bottom plan view of a needle retainer of the catheter insertion device illustrated in Fig. 13;

45 Fig. 17 is a side elevational view of the catheter insertion device illustrated in Fig. 16;

50 35 Fig. 18 is a side elevational view partially in section of an alternate embodiment of a catheter insertion device with a retractable needle according to

the present invention;

Fig. 19 is an enlarged fragmentary view of the catheter insertion device illustrated in Fig. 18, illustrating a locking button in a locked position;

Fig. 20 is a side elevational view partially in section of the catheter insertion device illustrated in Fig. 18, showing the needle in a retracted position;

Fig. 21 is an enlarged fragmentary view of the catheter insertion device illustrated in Fig. 20, illustrating the locking button in an unlocked position;

Fig. 22 is a sectional view of a second alternate embodiment of a catheter insertion device with a retractable needle according to the present invention;

Fig. 23 is a sectional view of the catheter insertion device illustrated in Fig. 22, illustrating the needle in a retracted position;

Fig. 24 is an enlarged fragmentary sectional view of the catheter insertion device illustrated in Fig. 23; and

Fig. 25 is an enlarged fragmentary sectional view of the catheter insertion device illustrated in Fig. 23.

Detailed Description of the Preferred Embodiments

Referring now to the Figs. 1-4 in general and to Fig. 1 specifically, a device for inserting an over-the-needle catheter 70 into a patient is designated generally 10. The device 10 includes a retractable needle 30 for piercing the skin of the patient to insert the catheter 70. After the catheter 70 is inserted into the patient, the needle 30 automatically retracts into the device 10 so that the sharpened tip of the contaminated needle is enclosed within the device to prevent inadvertent needle sticks.

Referring to Figs. 2-4, the device includes a generally cylindrical housing 20, the needle 30, a spring

5 60 biasing the needle rearwardly, and a needle retainer
40 releasably retaining the needle against the bias of
the spring. The needle is operable between two
10 positions, a projecting position and a retracted
5 position. In the projecting position, the needle 30
projects forwardly from the forward end of the housing
20. In the retracted position, the needle is retracted
15 into the housing so that the sharpened tip is enclosed
within the housing to prevent inadvertent contact with
20 the sharpened tip. When the needle is in the projecting
position, as shown in Fig. 2, the spring biases the
needle rearwardly toward the retracted position. The
needle retainer releasably retains the needle in the
15 projecting position, against the bias of the spring. The
needle retainer cooperates with the catheter 70, so that
25 when the catheter is removed from the device the needle
retainer automatically releases the needle and the needle
retracts into the housing, as shown in Fig. 4.

Referring now to Fig. 2, the elements of the device
30 will be described in greater detail. The housing is
generally cylindrical and the forward end of the housing
20 has a reduced diameter tapered nose 22. The catheter
70 is mounted on the nose 22. Accordingly, the nose 22
35 is tapered to cooperate with the internal taper of the
25 hub 72 of the catheter 70.

The catheter 70 includes a generally conical hub 72
and a flexible cannula 74 fixedly connected to the
40 catheter hub. The catheter 70 is mounted on the nose 22
of the housing so that the cannula 74 sheaths the forward
30 end of the needle. However, the sharpened tip of the
needle projects forwardly from the cannula so that the
45 sharpened tip is exposed prior to use.

When the catheter 70 is mounted on the nose 22, the
catheter hub 72 engages the needle retainer 40. The
50 needle retainer 40 is an elongated arm fixedly connected

5 with the needle 30. The arm projects forwardly through
an opening in the forward end of the housing, adjacent
the tip. The forward portion of the arm 40 forms a
10 follower portion 46. The follower portion projects
5 forwardly from the housing, through the opening in the
housing adjacent the nose 22 and engages the catheter hub
72.

15 The needle retainer 40 includes a ridge 45 that
protrudes radially outwardly, rearwardly of the follower
10 portion 46. The ridge 45 engages a lip 24 formed by the
opening through which the arm 40 projects adjacent the
nose. The ridge 45 operates as a latch to retain the
20 needle retainer and the attached needle against the bias
of the spring.

15 When the catheter 70 is mounted on the nose 22, the
25 catheter hub 72 engages the follower portion 46 of the
needle retainer 40 so that the ridge 45 is wedged into
engagement with the lip 24. In this way, when the
catheter is mounted on the device, the needle 30 is
30 20 maintained in the projecting position against the bias of
the needle. Removing the catheter 70 allows the needle
retainer to deflect radially inwardly disengaging the
ridge from the lip. In the present instance, the
35 rearward bias of the spring radially deflects the needle
25 retainer when the catheter is removed.

40 The needle retainer arm is formed of a flexible
plastic so that the arm is resiliently deformable. In
its relaxed state, the needle retainer arm 40 is disposed
into engagement with the lip 24 of the forward opening.
30 Preferably, the lip 24 is tapered rearwardly and the
ridge 45 on the needle retainer 40 forms a mating tapered
45 surface. These mating surfaces can be seen most clearly
in Figs. 3 and 4. Configured in this way, the rearward
axial biasing force of the spring acts upon the arm in
35 the form of a radial force component and an axial force

5 component. The radial force component urges the needle
retainer arm 40 inwardly so that the ridge 45 rides up
and over the lip 24 until the ridge is out of engagement
10 with the lip. The spring 60 then propels the needle
5 retainer and the attached needle rearwardly into the
housing so that the sharpened tip of the needle is
enclosed within the housing.

15 The device 10 further includes a fluid reservoir 50
attached to the rearward end of the needle, enclosing the
10 rearward end of the needle. The fluid reservoir 50 is in
fluid communication with the needle 30 and operates as a
20 flashback chamber. Accordingly, when the needle is
inserted into a patient's vein, blood flows through the
needle into the flashback chamber. The rearward end of
15 the flashback chamber 50 is sealed by a porous
25 hydrophobic vent plug 52. Air passes through the vent
plug to allow air to pass out of the flashback chamber
when the blood enters the flashback chamber. However,
30 the vent plug 52 is not permeable to blood to prevent
20 blood from leaking out of the flashback chamber. The
housing and the flashback chamber are formed of
translucent plastic so that the blood in the flashback
35 chamber serves as a visible indicator that the needle is
properly inserted into the patient's vein.

25 In the present instance, the flashback chamber 50
and the needle retainer 40 are integrally formed as a
unitary structure. The two elements are fixedly attached
40 to the needle by an adhesive such as UV curable epoxy.
The spring is disposed within the housing, circumscribing
30 the needle. The forward end of the spring bears against
the forward end of the housing, the other end of the
45 spring bears against the integral needle retainer and
flashback chamber.

35 In the present instance, the housing 20 is shorter
than the combined length of the needle 30 and the

5 flashback chamber 50. Accordingly, the rearward end of
the housing 20 is generally open, allowing the flashback
chamber to project rearwardly out of the housing when the
10 needle is retracted, as shown in Fig. 4. The device also
5 includes a locking or limiting feature to ensure that the
needle is not propelled rearwardly out of the housing.
Preferably, an aperture 26 sized to receive the forward
15 portion 46 of the needle retainer arm 40 is formed in the
side of the housing operates as the rearward lock. The
20 resilience of the needle retainer biases the needle
retainer radially outwardly. When the needle is
propelled rearwardly, the forward end of the needle
25 retainer 46 engages the aperture 26 so that the ridge 45
engages the rearward edge of the aperture, retaining the
needle against continued rearward displacement. In
30 addition, the forward end of the needle retainer 40
engages the forward edge of the aperture 26 to retain the
needle against forward displacement, so that the needle
cannot be re-extended after it is retracted.

30 20 When the catheter 70 is removed from the device and
inserted into a patient, blood from the patient may flow
out the rearward end of the catheter. Typically, once
the catheter is attached to a fluid reservoir, such as an
35 IV bag, the fluid pressure from fluid in the IV bag is
25 sufficient to prevent or limit the flow of blood from the
patient through the catheter. However, until the IV bag
is connected to the catheter, blood may leak out the
40 catheter. Therefore, it is desirable to plug the
catheter to prevent blood leakage after the catheter is
30 inserted into a patient.

45 Accordingly, preferably, the nose 22 forms a fluid-
tight seal with the interior of the catheter hub 72 when
the catheter is mounted on the nose. In this way, after
the catheter is removed from the housing and the needle
35 is retracted, the nose can be inserted into the catheter

5 to plug the catheter. Further, referring to Fig. 3,
preferably the nose extends forward of the follower
portion 46 of the needle retainer 40 so that the nose 22
10 substantially plugs the catheter immediately after the
5 needle is retracted. In addition, since the nose 22
projects forward of the follower portion 46, the needle
is never exposed during and after retraction.

15 Configured as described above, the device operates
as follows. Prior to use, the needle 30 is disposed in
10 the projecting position so that the sharpened tip of the
needle is exposed. The sharpened tip of the needle is
20 inserted into a vein of a patient. Blood flowing into
the flashback chamber 50 indicates to the medical
professional that the needle is inserted into a vein.
15 The catheter 70 is then threaded into the patient's vein
by advancing the catheter to remove the catheter from the
25 device 10. For this purpose, preferably, the catheter
hub 72 includes a protrusion 73 that the medical
30 professional can push forward with one of the fingers of
20 the hand holding the device. When the catheter is
advanced forward of the follower portion 46 of the needle
retainer 40, the needle retainer 40 deflects inwardly so
35 that the needle is released. The spring 60 then propels
25 the needle 30, the needle retainer 40 and the flashback
chamber 50 rearwardly so that the sharpened tip of the
40 needle is enclosed within the housing 20. If the medical
profession desires to do so, the nose 22 can then be
inserted into the catheter to replug the catheter to
prevent blood leakage.

30 Referring now, to Figs. 5-7 an alternative
embodiment, which is the preferred embodiment is
45 illustrated. Elements in the second embodiment that are
similar to elements of the first embodiment illustrated
in Figs. 1-4 and described above are designated with like
35 reference numbers, with the addition of 100s thereto.

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The second embodiment is designated generally 110. The device 110 includes a housing 120, a retractable needle 130, a spring 160 biasing the needle rearwardly, and a needle retainer 140 releasably retaining the needle against the bias of the spring. An over-the-needle catheter 170 is mounted on the forward end of the device 110. The needle retainer 140 cooperates with the catheter so that upon removing the catheter from the device 110, the needle is released, and the spring propels the needle rearwardly into the housing 120.

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The needle retainer 140 is configured similarly to the needle retainer 40 described in connection with the first embodiment. The needle retainer comprises an elongated resiliently flexible arm fixedly connected with the needle 30. The forward end of the needle retainer projects through an opening at the forward end of the housing adjacent the tip 122. The forward portion 146 of the needle retainer engages the side of the catheter hub 172. Similar to the first embodiment, the catheter hub 172 wedges the needle retainer arm radially outwardly so that a ridge 145 on the arm engages a lip 124 formed by the opening at the forward end of the housing. Accordingly, when the catheter 170 is removed from the device 110, the needle retainer 140 deflects inwardly to release the needle 30. The spring then propels the needle rearwardly into the housing 120. As shown in Fig. 7, the housing is elongated so that the entire length of the needle and the flashback chamber is enclosed within the housing in the retracted position.

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In this way, as with the first embodiment, the needle automatically retracts after use so that the medical professional need not perform any additional steps to ensure that the contaminated needle is safely enclosed. The step of inserting the catheter 170 into the patient is sufficient to effectuate retraction.

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5 However, as discussed further below, the medical professional may delay retraction if desired.

10 It may be desirable to allow the medical professional to delay retraction after the catheter is
5 inserted into the patient. Therefore, the device 110 includes a window 121 in the side of the housing 120.
15 The needle retainer 140 is disposed adjacent the window allowing the medical professional to manually engage the
10 needle retainer. If the medical professional desires to control retraction, the medical professional can apply
20 pressure to deflect the needle retainer radially inwardly so that the retainer abuts an interior wall 125. In this
15 way, the needle retainer is pinched between the grip of the medical professional and the interior wall to prevent
25 the needle from retracting into the housing. Once the medical professional releases the needle retainer, the
 needle retracts into the housing.

30 Preferably, the window 121 is located so that the medical professional engages the needle retainer when
20 grasping the device 110 for use. For this reason, preferably, a gripping portion is formed at the forward
35 end of the housing. The gripping portion is formed by a pair of opposing concavely curved surfaces along the
25 sides of the housing. The window 121 is formed in one of the opposing curved surfaces of the gripping portion.

40 The device operates as follows. Prior to use, the needle projects forwardly from the housing as shown in
30 Fig. 5. The medical professional grasps the gripping portion of the housing to hold the device 110. In doing
45 so, the medical professional engages the needle retainer through the window 121. The needle 130 is inserted
35 intravenously into a patient. Once blood flow is detected in the flashback chamber 150, the catheter is axially
50 advanced to insert the catheter into the patient. Once the catheter is axially advanced forward of the needle

5 retainer, the needle is freed to retract except for the
force being applied to the needle retainer by the medical
professional. If the medical professional does not want
10 to delay retraction the medical professional can release
5 the finger pressure on the needle retainer so that the
bias of the spring overcomes the finger pressure.
Alternatively, the medical professional can delay
15 retraction by maintaining his or her grip with sufficient
force to overcome the bias of the spring 160. Once the
20 medical professional releases the device, the needle
automatically retracts into the housing so that the
sharpened tip of the housing is enclosed. In this way,
25 the needle automatically retracts after the device is
used, and without any additional step, such as depressing
15 a button. At the same time, if the medical professional
desires to control retraction by delaying retraction, he
30 or she may do so, without performing any additional
steps. The natural steps of using the device allow such
control. However, even if the medical professional
35 desires to delay the retraction, the needle will
eventually automatically retract without any further
operation once the medical professional releases his or
her grip on the device.

35 The device 110 also includes an adjustable nose
25 piece 22. In the first embodiment, the nose 22 is
integrally formed with the housing. In the second
embodiment, the nose is a separate piece that is inserted
40 into a socket at the forward end of the housing that is
formed to receive the nose piece. The nose piece 122 may
30 be axially adjusted relative to the housing 120. By
adjusting the axial position of the nose piece, the
45 length of the exposed sharpened needle tip projecting
from the catheter cannula can be varied.

Referring now to Figs. 8-10 generally and to Fig. 8
35 specifically, a device for introducing a guide wire 270

5 into a patient is designated generally 210. The device
includes a needle 240 for piercing a vein of the patient.
The guide wire is inserted into the patient's vein
10 through the needle. After the guide wire is inserted
5 into the patient, the insertion needle automatically
retracts to that the contaminated needle is beyond the
reach of the medical professional using the device. In
15 addition, the medical professional using the device can
control retraction of the device to delay retraction if
10 desired. However, even if retraction is delayed,
retraction occurs automatically once the medical
20 professional puts the device down.

As shown in Fig. 3, the device includes a housing
220 having a reduced diameter tip 224. The needle 240
15 projects forwardly through an opening in the tip 224.
The rearward end of the housing 220 is generally closed,
25 having a reduced diameter opening through which the guide
wire 270 enters the interior of the housing. A rubber
seal 280 is disposed in the rearward end of the housing.
30 The guide wire 270 extends through a hole in the seal,
forming a fluid-tight seal with the seal 280. In
addition, seal 80 frictionally engages the guide wire to
frictionally connect the guide wire to the housing 220.

35 Rearward of the tip 224, the housing has a gripping
25 area 222 formed of a plurality of raised ridges. During
ordinary operation, the user grasps the gripping area to
hold the device during insertion of the guide wire.

40 A spring 260 circumscribes the needle, biasing the
needle 240 rearwardly toward a retracted position. A
30 needle retainer 230 releasably retains the needle in the
projecting position, in which the needle projects
45 forwardly from the housing, as shown in Fig. 8. The
needle retainer 230 comprises an elongated arm 232 that
is pivotally connected to the housing 220 by a pivot pin
35 233 that forms the pivot axis for the motion of the

5 needle retainer. A latch 235 is integrally formed on the
arm 232 on the end of the arm remote from the pivot pin
233. The latch 235 projects into the interior of the
10 housing.

5 Referring now to Fig. 9, the latch 235 engages a
flash back chamber 250 that is affixed to the rearward
end of the needle 240. The flashback chamber is a
15 generally cylindrical hollow chamber. The rearward end
of the needle has a side port 242 so that when the needle
20 pierces the patient's vein, blood flows through the side
port and into the flashback chamber to indicate to the
medical professional that the vein has been pierced.
Prior to advancing the guide wire 270, the guide wire
25 projects into the needle 240 so that the forward end of
the guide wire is rearward of the side port 242 in the
needle. In this way, the guide wire seals the rearward
end of the needle to prevent blood from leaking out the
rearward end of the flashback chamber. At the same time,
30 the guide wire does not block the side port so that blood
can flow through the needle and into the flashback
chamber.

The forward end of the flashback chamber 250 is
35 sealed by a porous vent that is air permeable, but does
not allow passage of blood from the flashback chamber.
25 The rearward end of the flashback chamber is generally
closed, having a small opening for receiving the guide
wire 270. The guide wire passes through the rearward
40 opening and into the needle. In this way, the guide wire
seals the opening in the rear of the flashback chamber to
prevent blood from leaking out of the flashback chamber.
30

As described above, the needle retainer pivots
45 between a latched position in which the needle retainer
retains the needle in the projecting position against the
rearward bias of the spring, and an unlatched position in
35 which the needle retainer releases the needle, allowing

5 the spring to propel the needle rearwardly into the
housing so that the sharpened end of the needle is
enclosed. The needle retainer 230 automatically pivots
10 from the latched position to the unlatched position after
5 the guide wire 270 is inserted into the patient. The
guide wire 270 prevents the needle retainer from pivoting
into the unlatched position until the guide wire is
15 inserted into the patient.

Specifically, a passageway 236 extends through the
10 latch 235 for receiving the guide wire. The guide wire
270 projects through the latch passageway 236 and into
20 the flashback chamber as shown in Fig. 10. While the
guide wire resides within the latch passageway, the latch
is prevented from pivoting into the unlatched position.
15 When the rearward end of the guide wire 270 is displaced
forwardly of the passageway so that the guide wire is
25 removed from the passageway, the guide wire no longer
retains the latch against being displaced radially
outwardly. The rearward bias of the spring 260 urges the
30 needle and attached flashback chamber rearwardly. This
in turn urges the latch radially outwardly, so that the
arm 232 pivots radially outwardly away from the needle.
The spring then propels the needle into the housing 220
35 as shown in Fig. 10.

25 As mentioned previously, the medical professional
operating the device 210, can optionally intervene to
delay retraction. Specifically, as shown in Fig. 8, in
40 the latched position the needle retainer 230 resides
within a slot in the gripping portion. In this way, when
30 the medical professional grasps the gripping portion 222,
the medical professional also grasps the arm 232 of the
45 needle retainer. As long as the medical professional
grasps the needle retainer, the needle retainer will not
pivot into the unlatched position. In this way, the
35 medical professional can delay retraction after the guide

5 wire is inserted into the patient. However, as soon as
the medical professional releases the needle retainer
230, the needle retainer will pivot into the unlatched
10 position and the spring will propel the needle into the
5 retracted position.

Configured in this way, the device operates as
follows. The needle 240 is inserted into a patient.
15 Blood flowing into the flashback chamber provides a
visual indication that the needle has been inserted into
20 a vein. The medical professional then advances the guide
wire 270 through the needle to insert the guide wire into
the patient's vein. As the guide wire is advanced, the
guide wire passes through the passage 236 that extends
15 through the latch 235. Once the guide wire 270 is
advanced forward of the latch, the needle retainer pivots
25 into the unlatched position and the spring propels the
needle rearwardly into the housing 220. If the medical
professional desires to delay retraction, the medical
professional grasps the needle retainer prior to
30 20 advancing the guide wire forwardly of the latch. The
guide wire is then advanced forwardly of the latch while
the medical professional continues to grasp the needle
retainer. When the medical professional desires to
35 retract the needle, the medical professional needle
25 simply releases his or her grip on the needle retainer.
The spring then automatically propels the needle
rearwardly into the retracted position.

40 Referring now to Figures 11 -- 12, a second
embodiment of a device for introducing a guidewire 370
30 into a patient is designated generally 310. The device
includes a needle 340 for piercing a vein of the patient.
45 The guidewire 370 is inserted into the patient's vein
through the needle. After the guidewire is inserted into
the patient, the insertion needle automatically retracts
35 into the housing 320 so that the contaminated needle is

5 beyond the reach of the medical professional using the
device. In addition, the medical professional using the
device can control retraction of the device to delay
10 retraction if desired. However, even if retraction is
5 delayed, retraction occurs automatically once the medical
professional puts the device down.

The guidewire 370 is preferably a substantially
15 inextensible semi-flexible wire. The forward end of the
guidewire is rounded, and preferably the wire is solid.
10 The wire is sized so that the diameter of the wire is
slightly smaller than the interior bore of the needle 340
20 so that the wire is slidable within the needle.

The device includes a hollow housing or barrel 320.
The needle 340 projects forwardly through an opening in
15 the forward end of the housing 340. The rearward end of
the housing 320 is generally closed, having a reduced
25 diameter opening through which the guidewire 370 enters
the interior of the housing. A rubber seal 380 is
disposed in the rear of the housing. The guidewire 370
30 extends through a hole in the seal 380, forming a fluid-
tight seal with the rubber seal. In addition, the seal
380 frictionally engages the guidewire to frictionally
connect the guidewire to the housing 320.

A spring 360 circumscribes the needle, biasing the
35 needle 340 rearwardly toward a retracted position, shown
25 in Fig. 12. A needle retainer 30 releasably retains the
needle in the projecting position, in which the needle
projects forwardly from the housing, as shown in Fig. 11.
40 The needle retainer 330 is an elongated arm integrally
formed from the housing, so that the arm 330 and the
30 housing 320 are formed of a one-piece construction. The
arm 330 is formed so that the arm is biased radially
45 outwardly toward the position illustrated in Fig. 12.

As shown in Fig. 11, prior to use the arm 330
35 projects into the interior of the housing 320. The

5 forward end of the arm 330 forms a latch 335 that engages
a flashback chamber 350 fixed to the rearward end of the
needle 340. The flashback chamber 350 is a generally
10 cylindrical hollow chamber. The rearward end of the
5 needle has a side port 342 so that when the needle
pierces the patient's vein, blood flows through the side
port and into the flashback chamber to indicate to the
15 medical professional that the vein has been pierced.
Prior to advancing the guidewire 370, the guidewire
20 projects into the needle 340 so that the forward end of
the guidewire is rearward of the side port 342 in the
needle. In this way, the guidewire seals the rearward
25 end of the needle to prevent blood from leaking out the
rearward end of the flashback chamber. At the same time,
15 the guidewire does not block the side port so that blood
can flow through the needle and into the flashback
30 chamber.

The forward end of the flashback chamber 350 is
sealed by a porous event that is here permeable, but does
30 not allow passage of blood from the flashback chamber.
The rearward end of the flashback chamber is generally
closed, having a small opening for receiving the
35 guidewire 370. The guidewire passes through the rearward
opening and into the needle. In this way, the guidewire
25 seals the opening in the rear of the flashback chamber to
prevent blood from leaking out of the flashback chamber.

As described above, the needle retainer pivots
40 between a latched position in which the needle retainer
retains the needle in the projecting position against the
30 rearward bias of the spring 360, and an unlatched
position in which the needle retainer releases the
45 needle, allowing the spring to propel the needle
rearwardly into the housing so that the sharpened end of
the needle is enclosed. The needle retainer 330
35 automatically pivots from the latched position to the

5 unlatched position after the guidewire 370 is threaded into the patient. The guidewire 370 prevent the needle retainer from pivoting into the unlatched position until the guidewire is threaded into the patient.

10 5 Specifically, the arm 330 includes a forward wire passageway 332 and a rearward wire passageway 334 for receiving the guidewire 370. The passageways 332,334 are located and oriented so that when the arm 330 is disposed in the latched position, illustrated in Fig. 11, the
15 10 passageways 332,334 are substantially co-axial with the needle 340. In this way, the guidewire 370 engages the needle retainer arm 330 to releasably retain the arm in the latched position, thereby releasably retaining the needle 340 in the projecting position against the bias of
20 15 the spring 360. While the guidewire 370 resides within one of the latch passageways 332,334, the arm is prevented from pivoting into the unlatched position. When the rearward end of the guidewire 370 is displaced forwardly of the forward wire passageway 332 so that the
30 20 guidewire is removed from the passageway, the guidewire no longer retains the arm against being displaced radially outwardly. The rearward bias of the spring 60 urges the needle 340 and attached flashback chamber 350 rearwardly. This, along with the radial bias of the arm
35 25 330 urges the arm radially outwardly, so that the arm pivots radially outwardly away from the needle. The spring then propels the needle into the housing 320 as shown in Fig. 12.

40 30 As shown in Fig. 11, preferably the arm 330 is bent to form a trough or depression. Preferably, the top surface of the trough is vertically spaced below the center line or axis of the needle 340. As shown in Fig.
45 11, a portion of the guidewire 370 between the wire passageways 332,334 is external of the housing 322 and
50 35 exposed for manual manipulation by the medical

5 professional. In this way, the medical professional can
both hold the device and feed the guidewire 370 into the
patient with one hand. Specifically, while holding the
10 device 310 with one hand, the medical professional can
5 engage the exposed portion of the wire between the
passageways 332,334 and displace the guidewire forwardly
to thread the guidewire through the needle 340 and into
15 the patient.

Referring now to Figs. 13-17 in general and to Fig.
10 13 specifically, there is shown a catheter insertion
device 410 for inserting a catheter 450 into a patient.
The device 410 has a needle 420 to guide the catheter 450
20 into a vessel of the patient. The insertion device 410
is adapted to automatically retract the needle 420 inside
15 the insertion device 410 when the operator removes the
catheter 450 from the device. In addition, the device is
25 configured to allow the operator to delay the retraction.
These features allow the operator to control retraction,
while ensuring that the needle automatically retracts
30 after use to render the needle non-reusable and safely
disposable.

The catheter insertion device 410 includes a
generally cylindrical hollow barrel or housing 430 having
35 a reduced diameter forward tip portion 434. The needle
25 420 is releasably retained so that the forward end of the
needle projects forwardly through a hole in the barrel
tip 434. The needle is operable between an extended
40 position and a retracted position. In the retracted
position, the needle is enclosed within the housing.

30 The catheter 450 is initially mounted on the forward
end of the catheter insertion device 410 with the needle
45 420 projecting from the front of the device through the
catheter. The catheter 450 comprises a cannula 452 and a
hub 454. The cannula 452 sheaths or receives the front
35 portion of needle 420, so that the sharpened point of the

5 needle extends slightly beyond the open end of the cannula.

10 The catheter 450 includes a flexible, elongated cannula 452 attached to the catheter hub 454. The
5 cannula 452 telescopingly engages the needle so that the cannula sheaths the needle, with the sharpened tip of the
15 needle 422 projecting beyond the forward end of the cannula. The rearward edge of the sharpened tip 422 is referred to as the heel of the needle bevel. The length
20 of the needle between the heel of the needle bevel and the forward end of the cannula is referred to as the lie length. Preferably, the lie length is adjustable.

In the present instance, the lie length is adjustable by maintaining the extended position of the
15 needle constant, and adjusting the position of the catheter 450 when the catheter is mounted on the barrel prior to use. The tip of the barrel 420 is adjustable to
25 provide for adjustment of the catheter.

30 Referring now to Fig. 15, the barrel 420 includes a displaceable tip 434. In the present instance, the tip
20 434 is a separate component that is inserted into an opening at the forward end of the barrel 430. The tip
35 434 includes an external circumferential flange 439 against which the rearward edge 455 of the catheter hub
25 454 seats. Therefore, varying the axial position of the tip 434 adjusts the axial position of the flange 439 thereby adjusting the lie length.

40 The tip 434 includes a generally cylindrical rearward portion having an external diameter that is
30 slightly less than the internal diameter of the forward portion of the barrel 430. A plurality of barbs 438
45 project from the external surface of rearward end of the tip 434. The barbs 438 engage the internal surface of the barrel 430 to connect the tip 434 to the barrel. The
35 axial position of the flange 439 is determined by the

5 distance that the rearward end of the tip is inserted
into barrel 430. By adjusting the amount the tip is
inserted, the axial position of the flange 439 is
10 adjusted, thereby adjusting the lie length.

5 As shown in Fig. 15, a generally cylindrical chamber
470 is attached to the rearward end of the needle. The
chamber 470 forms a flashback chamber. The flashback
15 chamber 470 is attached to the rearward end of the needle
420 so that the flashback chamber encloses the rearward
10 end of the needle 420. The rearward end of the flashback
chamber is closed by a porous vent plug 472. The vent
20 plug 472 allows the passage of air out of the chamber
470, while preventing blood from escaping from the
flashback chamber 470.

15 The needle 420 is biased rearwardly toward its
25 retracted position by a biasing element 460. In the
present instance, the biasing element is a coil spring
460 that surrounds the needle. The forward end of the
spring 460 bears against an internal shoulder formed in
30 the tip 434. The rearward end of the spring bears
20 against the flashback chamber 470, biasing the flashback
chamber and the attached needle rearwardly.
Alternatively, the spring 60 may be connected to the
35 needle by an adhesive, such as epoxy. The needle 420 and
25 flashback chamber 470 are releasably retained against the
bias of the spring 460 by a needle retainer or lever arm
440 that is pivotally connected to the housing 430.

40 The needle retainer 440 has a forward portion 444
and a rearward portion 448. In the present instance, the
30 forward portion 444 extends in the forward direction from
a pivot 442, and the rearward portion 48 extends
45 rearwardly from the pivot 442. The interior surface of
the forward portion 444 of the retainer 440 abuts with
the hub 454 of the catheter 450 when the catheter is
35 mounted on the insertion device 410. Preferably, the

5 forward portion 444 of the retainer 440 abuts or engages the external surface of the catheter hub 454.

Alternatively, the forward portion may engage the internal surface of the catheter hub 454. The rearward
10 portion 448 of the needle retainer 440 is located rearwardly from the pivot point and catheter 450, when the catheter is mounted on the insertion device.

The rearward portion 448 of the needle retainer 440
15 comprises a release lever having a latch 446 formed thereon. The lever is pivotable between a locked position and an unlocked position. In the locked
20 position, the release lever extends generally parallel to the longitudinal axis of the device 410. The latch 446 on the end of the release lever passes through an opening
25 432 in the side of the barrel 430, so that the rear end of the flashback chamber 470 abuts the latch to retain the needle in its extended position.

It is desirable to align the sharpened tip 422 of the needle 420 so that the bevel of the sharpened tip is
30 circumferentially located relative to the barrel 430, as illustrated in Fig. 13. Specifically, preferably, the sharpened tip is circumferentially located so that the forward-most point of the sharpened tip is vertically
35 positioned below the heel of the tip bevel. In the present instance, the flashback chamber 470 is configured to cooperate with needle retainer to facilitate aligning the bevel of the needle, as described below.

The flashback chamber 470 is generally cylindrical, and includes a flat surface extending along the length of
40 the flashback chamber. The desired circumferential orientation of the needle bevel is located relative to the flat on the flashback chamber when the flashback chamber is connected to the needle. Referring to Fig.
45 15, the rearward portion 448 of the needle retainer includes a generally planar surface or ledge 449 that
50

5 cooperates with the flashback chamber 470 to
circumferentially align the needle 420 relative to the
barrel 430. As shown in Fig. 15, when the needle
10 retainer 440 is disposed in the latched position, the
5 flat on the flashback chamber 470 is aligned with and
engages the ledge 449 of the needle retainer. In this
way, the flashback chamber 470 and the attached needle
15 420 are circumferentially located relative to the needle
retainer, and in turn to the barrel 430.

10 The engagement between the forward portion 444 of
the needle retainer lever and the catheter hub 454
20 prevents the lever from pivoting to its unlocked position
when the catheter is mounted on the insertion device.
The rear portion 48 of the retainer 440 is preferably
15 biased to pivot away from the side of the housing 430.
In the present instance, the face of the latch 446 that
25 engages the flashback chamber 470 is angled so that a
portion of the rearward bias of spring 460 is transferred
to the lever biasing the lever radially outwardly. After
30 the catheter 450 is removed past the end of the lever,
the retainer is free to pivot into its unlocked position,
thus moving the latch 446 out of engagement with the rear
end of the needle 420. The spring 460 then propels the
35 needle rearwardly into the housing 430.

25 The operator can control retraction of the needle,
if desired, as follows. The needle retainer 440 includes
a rib 445 that is transverse the longitudinal axis of the
40 needle retainer lever. As shown in Figs. 13 and 14, the
barrel 430 includes a gripping portion comprised of a
30 plurality of parallel spaced apart ribs 431. The needle
retainer rib 445 is generally parallel to the gripping
45 ribs 431 so that the needle retainer rib 445 forms part
of the gripping portion. In this way, if the operator
desires to control retraction of the needle, the operator
35 grasps the rib 445 of the needle retainer when grasping

5 the gripping portion of the device 410.

By grasping the needle retainer rib 445, the operator impedes pivoting of the needle retainer 440 from the locked position to the unlocked position. After the
10 operator inserts the catheter 450 into the patient, the forward portion 444 of the needle retainer is disengaged from the catheter, thereby allowing the needle retainer
15 to pivot toward the unlocked position. However, the operator's grasp of the needle retainer rib 445 operates
10 as an override preventing the needle retainer from pivoting into the unlocked position. The operator can control retraction by maintaining an inward force on the
20 needle retainer rib 445 until retraction is desired. Once the operator releases the needle retain rib 445

15 after the catheter 450 has been disengaged from the needle retainer 440, the needle retainer is free to pivot
25 into the unlocked position so that the spring 460 propels the needle 420 rearwardly into the barrel 430. In this way, the device prevents retraction from occurring until
30 after the catheter 450 is disengaged from the housing of the insertion device. In addition, the device allows the operator to control the timing of retraction, while
ensuring that retraction occurs after use of the device.

35 The catheter insertion device is initially provided
25 in the configuration shown in Fig. 13. The operator of the catheter insertion device 410 first uses the needle point 422 to pierce a blood vessel of the patient. When
40 the needle point 422 pierces the patient's blood vessel, blood flows through the needle 420 and collects in the transparent flashback chamber 470. The appearance of
30 blood in the flashback chamber 470 serves as a visible indication to the operator that a blood vessel has been
45 appropriately pierced, and that the catheter 450 is properly positioned. The operator then slides the
35 catheter hub 454 off of the forward end of the device

5 410, in the direction of the pointed end 422 of the
needle 420, to insert the catheter lumen 452 into the
patient's blood vessel. This motion of removing the
10 catheter hub 454 from the device causes the retainer 440
5 to automatically pivot out of contact with the end of the
needle when the rim 455 of the catheter hub passes the
end of lever 444. However, the operator can temporarily
15 override the automatic retraction by grasping the needle
retainer rib 445 prior to removing the catheter hub.
20 Once the operator releases the needle retainer rib 445,
the needle retainer pivots out of engagement with the
needle 420. The needle is thereby released and withdrawn
into the barrel 430 of the catheter insertion device 410
under the bias of spring 460. The operator need not
15 perform any additional action to effectuate retraction of
the needle other than that required by a normal catheter
insertion procedure. At the same time, the operator can
intervene to delay retraction, if desired.

Referring to Fig. 15, the tip 434 further includes a
30 20 constricted portion 435 having an internal diameter
slightly larger than the external diameter of the needle
420. The close fit between the constricted portion 435
and the needle limits leakage of blood into the barrel
35 430 during a replugging step, as described further below.
25 In addition, an external circumferential rib 437
protrudes radially from the front end of the tip 434.
The rib 437 cooperates with the internal cavity of the
40 catheter hub 454 to provide a fluid-tight seal. The
internal cavity is tapered, having a major diameter that
30 is greater than the diameter of the rib 437 on the tip
434. Preferably, a substantially cylindrical zero draft
45 zone is formed at the forward-most portion of the
internal cavity. The zero draft zone has an internal
diameter that is similar to the external diameter of the
35 rib 437 on the tip 434. In this way, when the catheter

5 450 is mounted on the barrel 430, the rib 437 engages the zero draft zone to form a fluid-tight seal.

10 After the catheter has been inserted into the patient and the needle 420 has been retracted, the tip
5 434 of the device can be inserted into the catheter 450 to replug the catheter to prevent blood from leaking out of the catheter. For this reason, the catheter 450
15 and/or the forward end of the needle retainer 440 are configured to facilitate pivoting of the needle retainer
20 so that the forward end of the needle retainer does not interfere with replugging of the catheter. Specifically, the forward edge of the needle retainer is rounded so
25 that the forward portion 444 of the needle retainer 440 pivots downwardly from the perspective of Figs. 13 and 15
15 when the needle retainer engages the rim 455 of the catheter 450. Alternatively, the rim 455 can be rounded
25 or tapered to facilitate pivoting of the needle retainer 440 upon forward axial displacement of the tip 434
30 relative to the catheter 450 after the catheter has been removed from the device a sufficient amount to disengage
20 the needle retainer from the needle 420.

35 The catheter 450 is replugged after retraction by inserting the tip 434 of the barrel 430 into the catheter cavity so that the circumferential rib 437 engages the
25 zero draft zone. The rib 437 and the zero draft zone cooperate to form a fluid-tight seal so that blood does not leak from the catheter around the tip 434. In
40 addition, the retracted needle 420 forms a seal with the constricted portion 435 of the tip 434 to reduce or
30 eliminate blood leakage from the catheter 450 into the barrel 430. In the retracted position, the latch 446
45 deflects and/or deforms the needle.

50 The tip 434 further includes an external circumferential depression or recess 436. Initially, the
35 catheter 450 encloses the tip 434 so that the operator

5 cannot see the recess 436. As the operator removes the
catheter 450 from the tip 434, the recess 436 is
uncovered so that the operator can see the recess. After
10 the recess 436 is uncovered, continued removal of the
5 catheter 450 displaces the catheter beyond the forward
end of the needle retainer 440, so that the needle
retainer pivots into the unlatched position. In this
15 way, the recess operates as a visual indicator to the
operator, providing a visual signal that continued
20 forward displacement of the catheter will cause needle
retraction. Preferably, the recess 436 is textured to
enhance the visual distinction between the recess and the
rest of the external surface of the tip. Alternatively,
25 a different visual indicator can be provided, such as a
circumferential colored line located on the tip 434
axially rearwardly of the forward end of the needle
retainer 440.

Referring now to Figs. 18-20, there is shown an
alternate embodiment of a catheter insertion device 510.
30 The alternate embodiment shown in Figs. 17-20
incorporates elements that are similar to elements in the
first embodiment described above in connection with Figs.
13-17. Parts in Figs. 18-20 that are similar to the
35 parts in Figs. 13-17 are numbered by the same number
designator with the addition of 500's thereto.

The catheter insertion device 510 includes an
insertion needle 520 projecting forwardly from a barrel
40 or housing 530. The needle 520 is releasably retained by
a needle retainer 540 comprising a release lever. The
30 needle retainer 540 engages a catheter 550 mounted on the
tip 534 of the housing 530. In this manner, the catheter
45 550 impedes pivoting of the needle retainer 540 and
prevents retraction of the needle 520 while the catheter
is mounted on the housing 530 of the device 510.

35 As in the embodiment described above in connection

5 with Figs. 13-17, the catheter insertion device 510 in
Fig. 18 is also operable to automatically retract the
needle without manual intervention or requiring a
10 separate step for retraction. The needle retainer 540 is
5 biased toward an unlatched position, so that when the
catheter 550 is removed from the insertion device 510,
the needle retainer 540 automatically pivots into its
unlatched position, releasing the needle 520. The spring
15 560 then propels the needle 520 rearwardly into the
housing 530, so that the sharpened tip of the needle 520
10 is safely enclosed within the housing.

20 In addition, as in the previous embodiment, the
device 510 includes an exposed, manually actuatable surface
that allows the operator to intervene to delay retraction
15 if desired. Specifically, the device includes a control
25 button 580 that engages a pawl 549 connected to the
needle retainer 540. The control button 580 operates
between a locked position and an unlocked position. In
the locked position the control button engages the pawl
30 549 on the needle retainer 540 preventing the needle
retainer from pivoting into the unlatched position to
release the needle 520. The control button is
displaceable toward the unlocked position, which
35 corresponds to the needle retainer 540 being in the
25 unlatched position.

The control button 580 and pawl 549 have mating
tapered surfaces. When the needle retainer 540 pivots,
40 the mating tapered surfaces of the pawl and control
button transfers a vertical force to the button,
30 displacing the control button upwardly into the unlocked
position. Accordingly, absent operator intervention,
45 when the catheter 550 is removed from the housing 530,
the needle retainer 540 pivots into the unlatched
position, displacing the control button into the unlocked
35 position. The needle then retracts into the housing.

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The operator can intervene to delay retraction by depressing the control button 580 before the catheter is removed. The downward force applied by the operator on the control button locks the pawl 549 in place, preventing the needle retainer from pivoting. After the catheter is removed from the housing, the needle retainer retains the needle as long as the operator depresses the control button. As soon as the operator releases the control button, the pawl is free to rotate, so that the needle retainer pivots into the unlatched position and the needle retracts. In this way, retraction of the insertion needle occurs automatically after the device is used, but the operator can delay retraction if desired.

The device 510 also illustrates an alternate arrangement for the flashback chamber 520. The flashback chamber 520 can be configured as in the previous embodiment in which the flashback chamber 470 encloses the rearward open end of the needle 420, and the needle retainer 440 engages the flashback chamber.

Alternatively, in the present embodiment, the rearward end of the needle 520 projects rearwardly from the flashback chamber 570, and the needle retainer 540 engages the rearward end of the needle. The rearward end of the needle is plugged to prevent blood from leaking into the housing. In addition, a side port is formed in the side of the needle, and the flashback chamber encloses the side port. Blood from the patient flows through the side port and into the flashback chamber, serving as a visual indicator that the patient's artery has been pierced.

Referring now to Figs. 22-25, there is shown another alternative embodiment of a catheter insertion device 610. The device 610 incorporates elements that are similar to ones previously described. Such elements are designated with the same number designations with the

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5 addition of 600's thereto.

10 The catheter insertion device 610 includes an
insertion needle 620 projecting forwardly from a barrel
or housing 630. The needle 620 is releasably retained by
5 a pivotable needle retainer 640 comprising a release
lever. One end of the needle retainer 640 engages a
catheter 650 mounted on the tip 634 of the housing 630.
15 In this arrangement, the catheter 650 impedes the needle
retainer 640 from releasing the needle 620 while the
20 catheter is mounted on the housing 630 under the retainer
640.

20 As in the embodiment described above in connection
with Figs. 13-21, the catheter insertion device 610 in
Fig. 22 is also operable to automatically retract the
15 needle without manual intervention or requiring a
separate step for retraction. The needle retainer 640 is
25 biased toward an unlatched position, so that when the
catheter 650 is removed from the insertion device 610,
the needle retainer 640 automatically pivots into its
30 unlatched position, releasing the needle 620. The spring
660 then propels the needle 620 rearwardly into the
housing 630, so that the sharpened tip of the needle 620
is safely enclosed within the housing.

35 In addition, as in the previously described
25 embodiments, the device 610 includes an exposed, manually
actuatable surface that allows the operator to intervene to
delay retraction if desired. Specifically, the housing
40 includes a gripping portion 691 providing a surface for
the operator to grasp the device 610. The needle
30 retainer 640 is located adjacent the gripping portion 631
so that the operator can readily engage the needle
45 retainer to prevent the needle retainer from pivoting
into the unlatched position.

Referring to Figs. 22 and 23, the housing 630
35 includes the gripping portion 631, which is formed of a

5 plurality of parallel spaced apart ribs. The ribs form a
convex curved surface providing a secure anti-slip
surface. As shown in Fig. 13, the housing may include
10 opposing gripping surface for gripping the device. In
5 the present instance, the barrel includes the gripping
portion 631 on one side of the housing, and the rearward
portion 648 of the needle retainer 640 is located on the
other side of the housing, opposing the gripping portion.
15 The exposed surface of the rearward portion 648 of the
10 needle retainer 640 is configured and textured similar to
the gripping portion 631. Accordingly, when the operator
grasps the device for use, the operator's normal grip on
20 the device operates to depress the rearward portion of
the needle retainer. As long as the operator depresses
15 the rearward portion of the needle retainer, the operator
prevents the needle retainer from pivoting radially
25 outwardly to release the needle for retraction.

The device 610 also includes a telescoping barrel to
reduce the overall length of the housing prior to use.
30 Alternatively, the device 610 can use a single piece
20 housing as described above in the foregoing devices 410,
510.

35 The housing 630 of the device 610 comprises two
components, an outer sleeve 690 and an inner sleeve 695.
25 The inner sleeve 695 telescopes within the outer sleeve
690. Prior to use, the inner sleeve 695 is enclosed
within the rearward end of the outer sleeve 690. When
40 the needle 620 is retracted, the flashback chamber 670
and attached needle engages the inner sleeve, displacing
30 the inner sleeve rearwardly as the needle retracts. In
this way, the outer sleeve telescopes outwardly extending
45 the length of the housing to accommodate the entire
length of the needle.

The housing includes a forward stop to prevent the
35 inner sleeve 695 from being reinserted into the outer
50

5 sleeve 690. The housing further has a rearward stop to prevent the inner sleeve from being displaced rearwardly beyond the rearward edge of the outer sleeve.

10 A pair of resilient locking tabs 697 formed in the
5 side of the inner sleeve 695 cooperates with the rearward edge of the outer sleeve 690 to operate as the forward stop. The locking tabs 697 are biased radially
15 outwardly. When the inner sleeve 695 is enclosed within the outer sleeve 690, the locking tabs 697 engage the
10 inner surface of the outer sleeve so that the locking tabs are substantially flush with the outer surface of the inner sleeve. When the inner sleeve is displaced rearwardly so that the locking tabs are rearward of the outer sleeve, the locking tabs flex radially outwardly as
20 shown in Figs. 23 and 24. Accordingly, attempts to
15 displace the inner sleeve forwardly after retraction causes the locking tabs to engage the rear edge of the outer sleeve, thereby preventing forward displacement.

30 An annular lip 693 on the outer sleeve 690
20 cooperates with a circumferential flange 696 on the inner sleeve 695 to operate as the rearward stop. Referring to Figs. 23 and 24, the annular lip 693 projects radially inwardly from the rearward edge of the outer sleeve 690.
35 The circumferential flange 696 projects radially
25 outwardly from the forward edge of the inner sleeve 695. When the inner sleeve is displaced rearwardly, the circumferential flange 696 engages the annular lip 693
40 impeding further rearward displacement of the inner sleeve.

30 The terms and expressions which have been employed are used as terms of description and not of limitation.
45 There is no intention in the use of such terms and expressions of excluding any equivalents of the features shown and described or portions thereof. It is
35 recognized, however, that various modifications are

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possible within the scope and spirit of the invention as
defined by the appended the claims.

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What is claimed is:

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1. A medical device, comprising
a hollow housing;
a catheter mounted on the housing;
a needle having a sharpened tip operable between an
extended position extending forwardly from the
housing and a retracted position in which the
sharpened tip of the needle is enclosed within
the housing;
a biasing element biasing the needle toward the
retracted position; and
a needle retainer fixedly connected with the
insertion needle and releasably retaining the
insertion needle in the extended position,
comprising an elongated arm having a follower
portion engaging the catheter;
wherein the needle retainer releases the needle upon
removal of the catheter from the housing such
that the biasing element propels the needle
rearward.
2. The medical device of claim 1 comprising a lock for
locking the needle in the retracted position.
3. The medical device of claim 1 wherein the elongated
arm comprises a latch releasably engaging the
housing.
4. The medical device of claim 1 comprising a flashback
chamber integrally formed with the needle retainer.
5. The medical device of claim 1 wherein the needle
retainer is constrained to pivotable motion prior to
retraction of the needle.

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6. A medical device, comprising:

a hollow housing;;

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a needle operable between an extended position
extending forwardly from the housing and a
retracted position in which the needle is
enclosed in the housing;

15

a biasing element biasing the needle toward
the retracted position; and

a lever mounted on the housing, pivotable between
a locked position and an unlocked position;

20

a guide wire projecting through the lever and the
needle, wherein the wire engages the lever to
prevent the lever from pivoting into the
unlocked position;

25

wherein inserting the guide wire into a patient
releases the lever from the guide wire whereupon the
lever pivots into the unlocked position and the biasing
elements propels the needle rearwardly into the housing.

30

7. The medical device of claim 6 wherein the needle
retainer includes an exposed manually operable
surface that can be engaged by the user to delay
retraction.

35

8. The medical device of claim 6 comprising a fluid
chamber in fluid communication with the needle.

40

9. The medical device of claim 6 wherein the lever is
fixedly connected to the housing.

45

10. A method for inserting a guide wire into a patient,
comprising the steps of:

providing a device having a housing, a needle, a
needle retainer for releasably retaining the
needle so that the needle projects forwardly

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from the housing, and a guide wire releasably
engaging the needle retainer;
inserting the guide wire into the patient so that
the guide wire is displaced out of engagement
with the needle retainer;
retracting the needle into the housing.

10

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11. The method of claim 10 comprising the steps of:
selectively manually engaging the needle retainer to
impede retraction of the needle;
releasing the selective manual engagement with the
needle retainer to disengage the needle
retainer and the needle.

20

12. A medical device, comprising:

25

a hollow housing;

a catheter mounted on the housing;

a needle operable between an extended position
extending forwardly from the housing and a
retracted position in which the needle is
enclosed in the housing;

30

a biasing element biasing the needle toward
the retracted position; and

35

a lever mounted on the housing, pivotable between
a locked position and an unlocked position,
wherein the lever has a forward portion and a
rearward portion, the forward portion engaging
the catheter preventing the lever from pivoting
into the unlocked position, and the rearward
portion retaining the needle against the bias
of the biasing element wherein upon removal of
the catheter from the housing the catheter
disengages the lever allowing the lever to
pivot into the unlocked position so that the
rearward portion disengages the needle and the
biasing element propels the needle rearwardly

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into the housing;
an exposed surface manually operable to retain the
needle retainer in the latched position.

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13. The medical device of claim 12 wherein the catheter
has an internal surface and an external surface, and
the forward portion of the lever engages the
catheter external surface.

15

14. The medical device of claim 12 comprising a fluid
chamber in fluid communication with the needle.

20

15. The medical device of claim 12 wherein the lever is
fixedly connected to the housing.

25

16. The medical device of claim 12 wherein the rearward
portion of the lever is spaced rearwardly from the
catheter.

30

17. The medical device of claim 12 wherein the catheter
is operable between a mounted position in which the
catheter is mounted on the housing, and a removed
position in which the catheter is removed from the
housing, wherein the device comprises an indicator
associated with the catheter operable to provide an
indication signal when the catheter is displaced
into a position intermediate the mounted position
and the removed position.

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18. The medical device of claim 12 wherein the
indication signal is audible or tactile.

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19. The medical device of claim 17 wherein the
indication signal is visual.

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20. A medical device comprising:

a hollow housing;

a catheter mounted on the housing;

10

a needle operable between an extended position
extending forwardly from the housing and a
retracted position in which the needle is
enclosed within the housing;

15

a biasing element biasing the needle rearwardly into
the retracted position;

20

a needle retainer operable between a latched
position and an unlatched position, wherein in
the latched position the needle retainer
retains the needle in the extended position
against the bias of the lever;

25

an exposed surface manually operable to retain the
needle retainer in the latched position.

21. A method for inserting an IV catheter, comprising
the steps of:

30

providing a catheter insertion device having a
housing, a catheter hub removably mounted on
the housing, a needle, and a needle retainer
for releasably retaining the needle so that the
needle projects forwardly from the housing;
disengaging the engagement of the catheter with the
housing;

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selectively manually engaging the needle retainer to
impede retraction of the needle;
releasing the selective manual engagement with the
needle retainer to disengage the needle
retainer and the needle;

45

retracting the needle into the housing.

22. A medical device, comprising:

a hollow housing;

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a needle having a sharpened tip operable between an

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extended position extending forwardly from the housing and a retracted position in which the sharpened tip of the needle is enclosed to prevent inadvertent contact with the sharpened tip;

15

a biasing element biasing the needle toward the retracted position;

20

an intravenously insertable element carried by the needle; and

25

retaining means releasably retaining the needle in the extended position, wherein the needle retainer releases the needle upon insertion of the intravenously insertable element into the patient such that the biasing element propels the needle rearward into the retracted position.

30

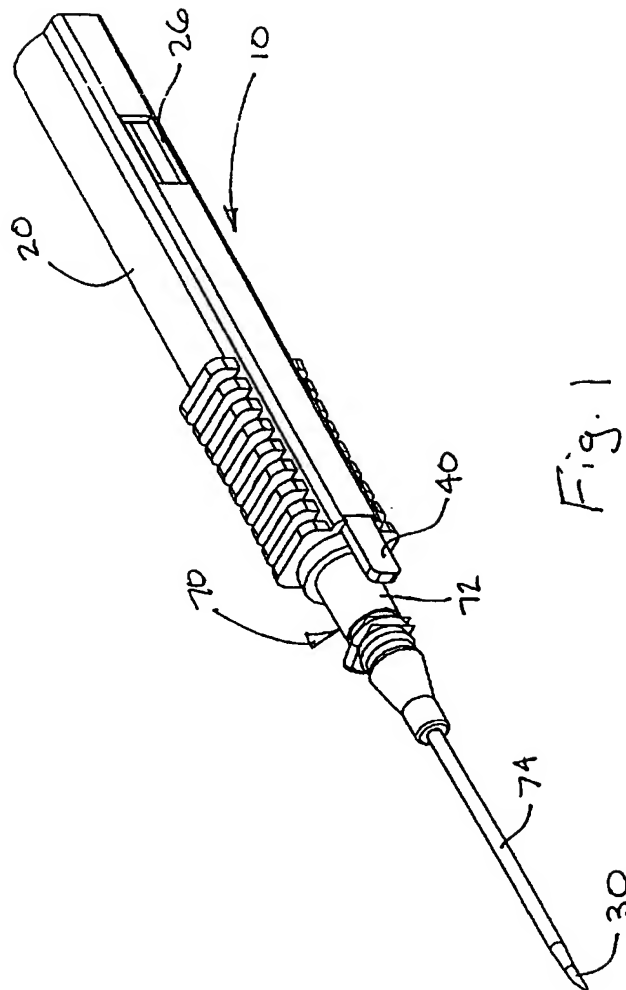
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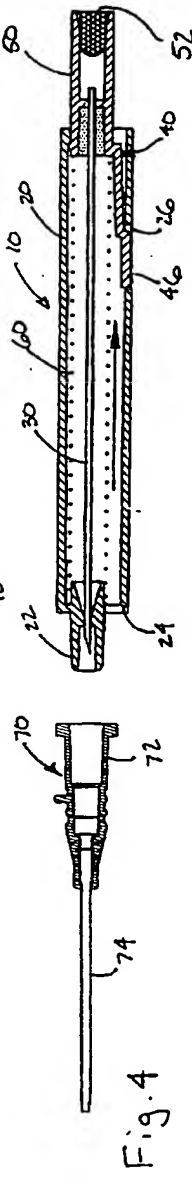
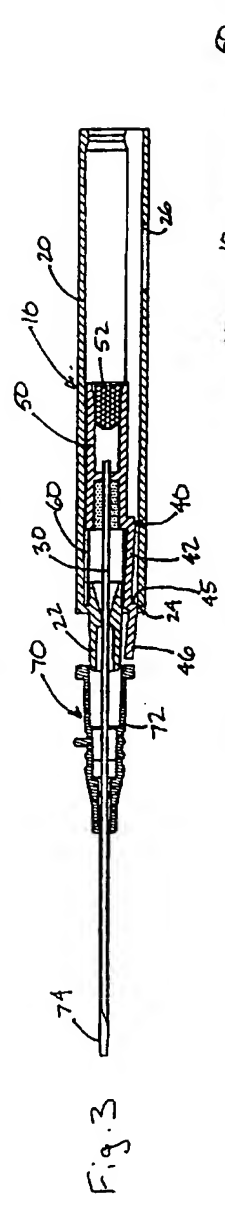
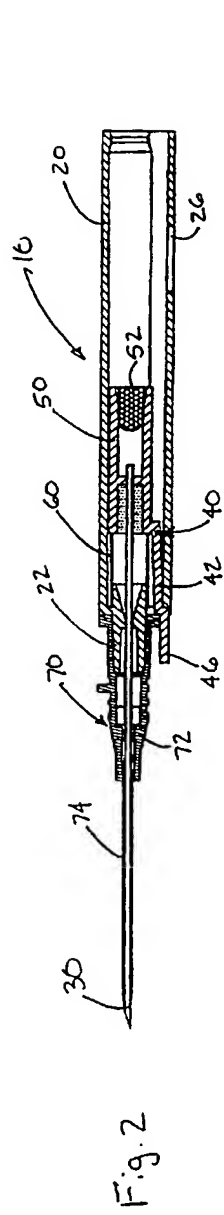
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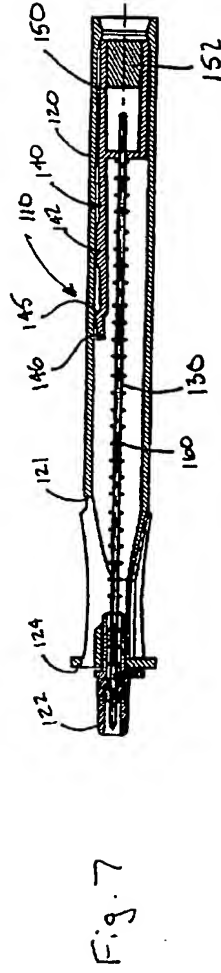
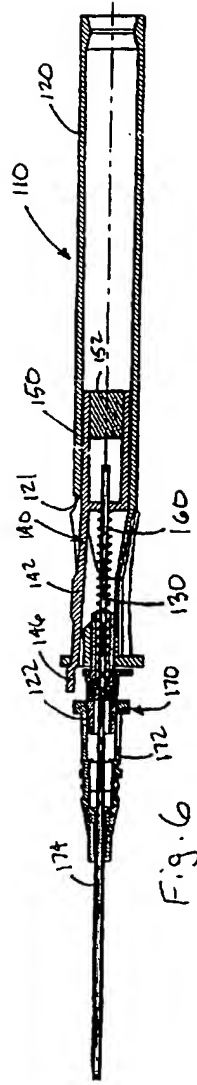
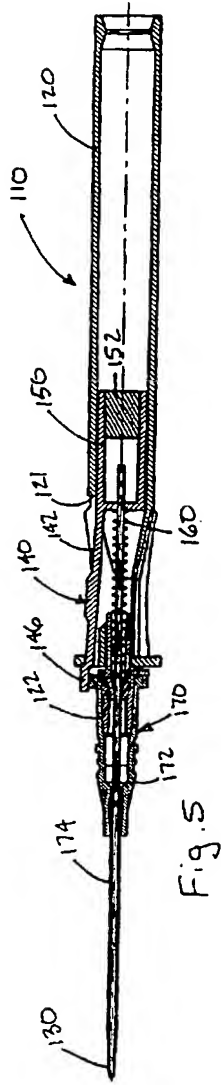
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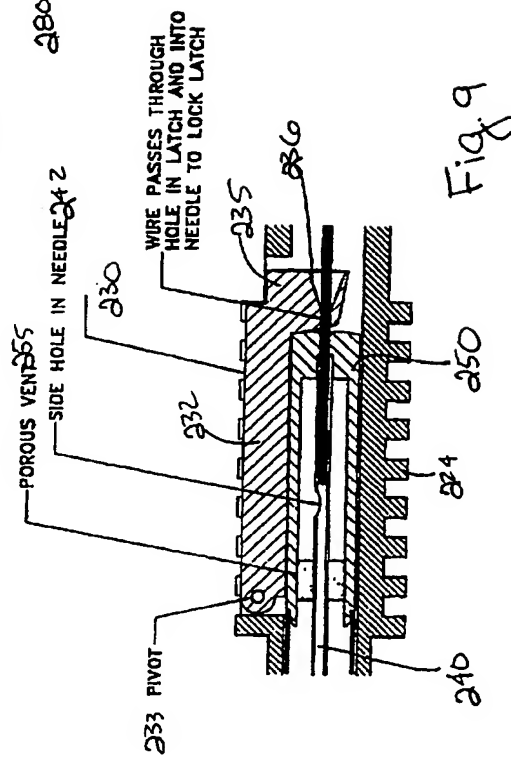
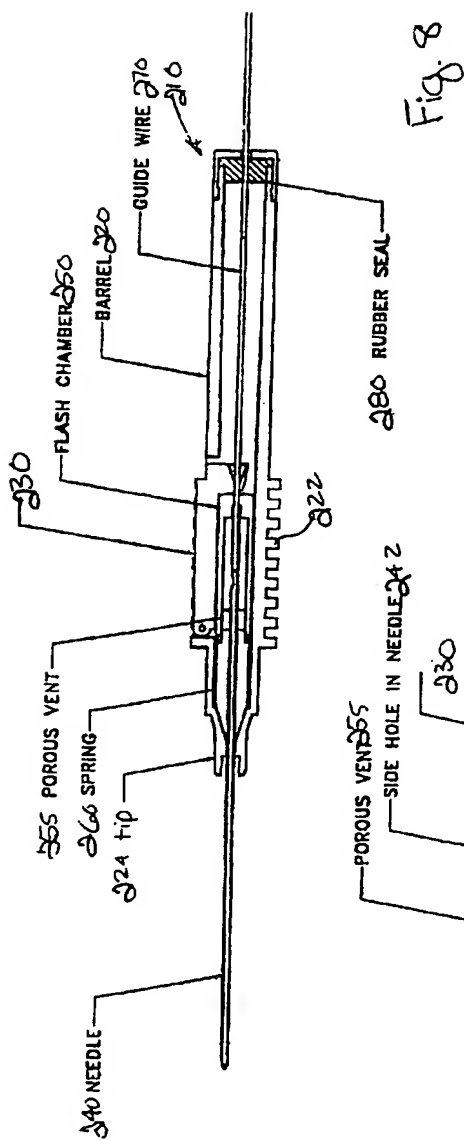
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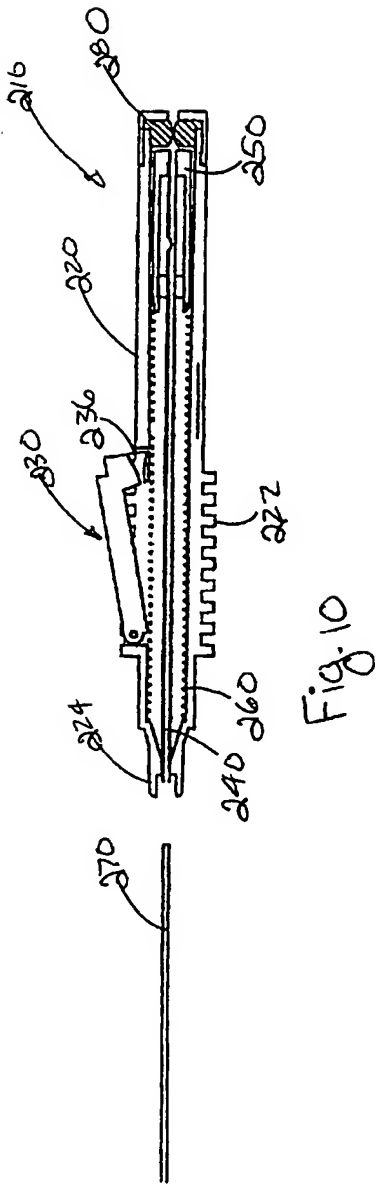
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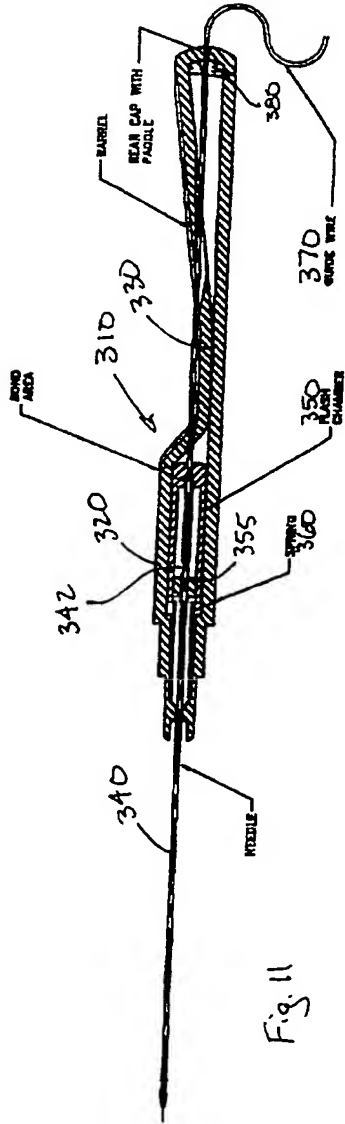


Fig. 11

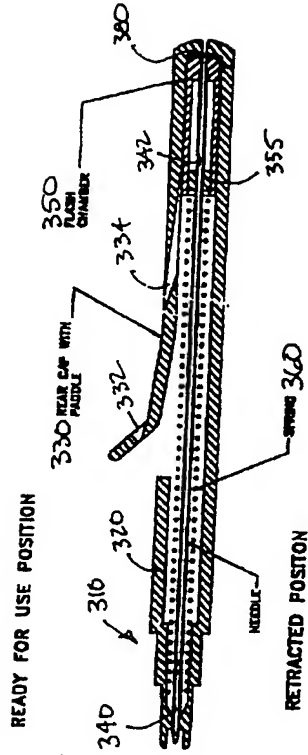
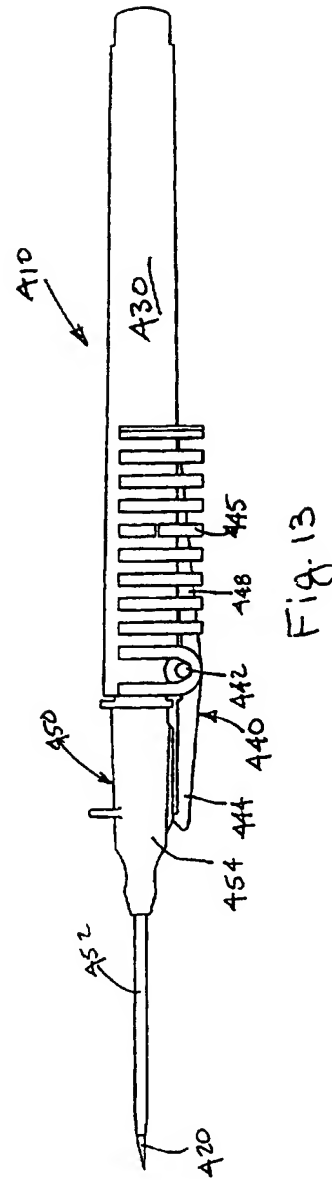
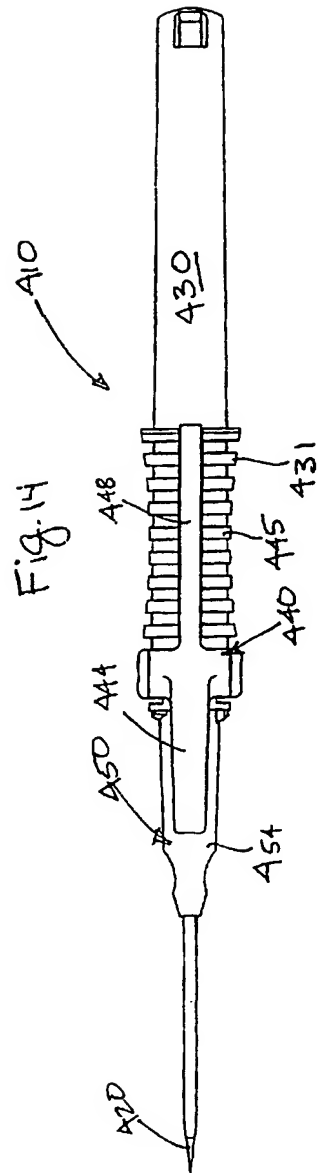


Fig. 12

NOTE: GUIDE WIRE IS THREADED OUT FRONT OF NEEDLE AND INTO VEIN, ALLOWING PADDLE TO ROTATE AND NEEDLE TO RETRACT. GUIDE WIRE PREVENTS PADDLE FROM ROTATING UNTIL REMOVAL.



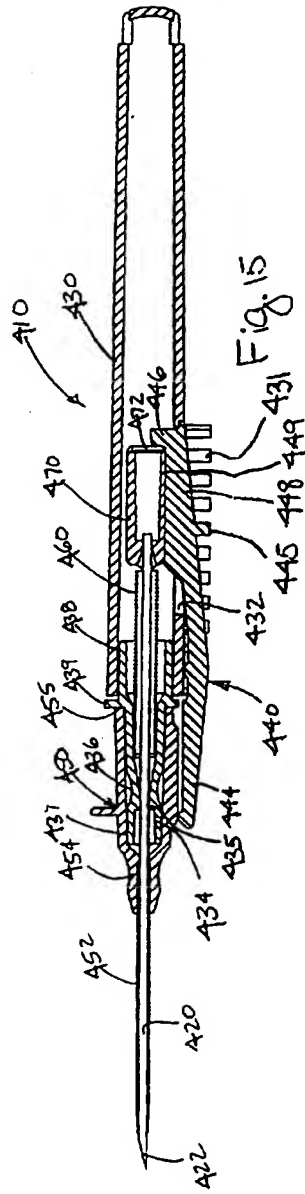


Fig. 15

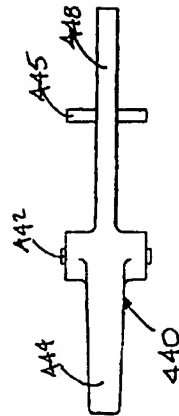


Fig. 16

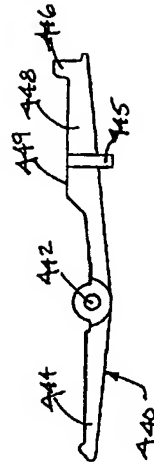


Fig. 17

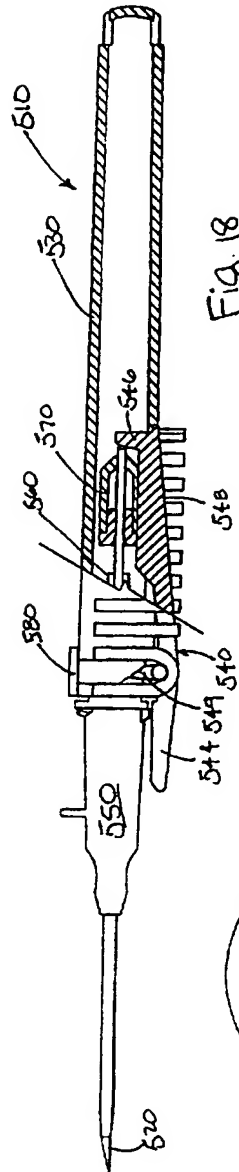


Fig. 18

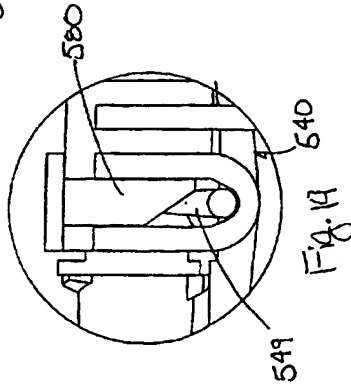


Fig. 19

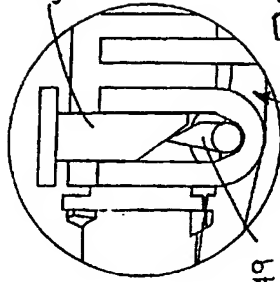


Fig. 20

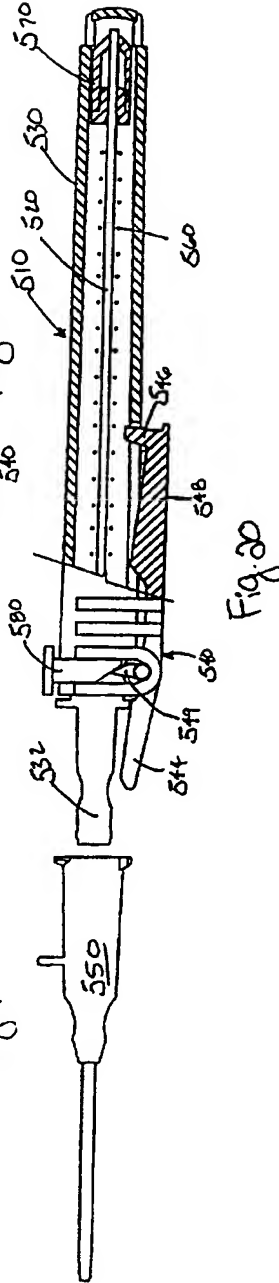
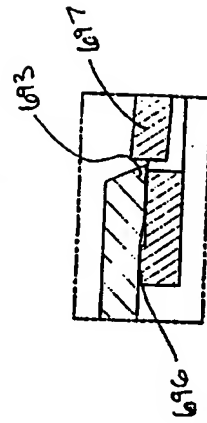
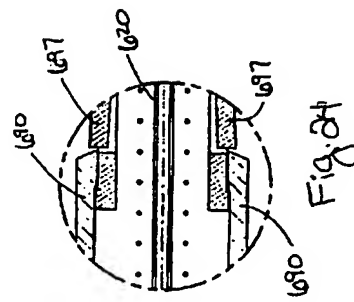
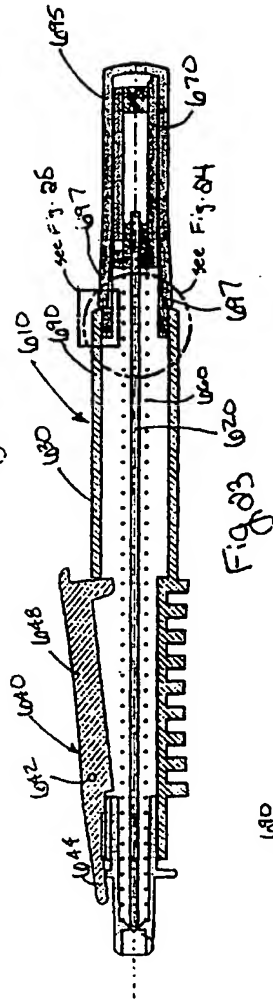
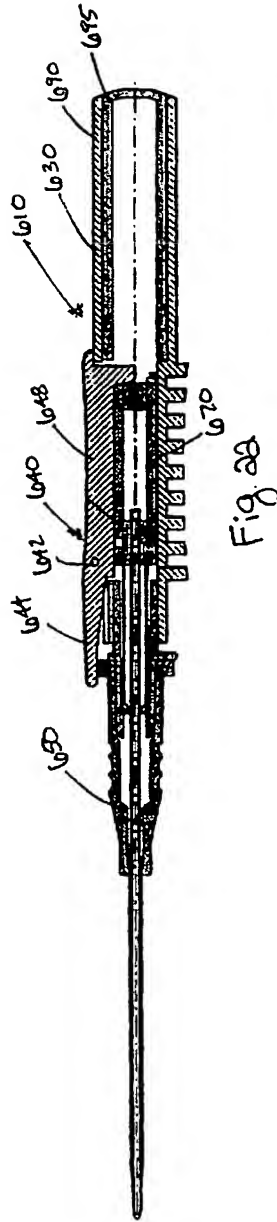


Fig. 21



INTERNATIONAL SEARCH REPORT

International application No.
PCT/US99/10609

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) : A61M 5/00, 32, 178
US CL : 604/110, 164, 168, 193

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/917, 919; 604/110, 164, 165, 168, 170, 171, 195, 198, 263, 264, 528

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
APS, WEST

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,575,777 A (COVER et al) 19 November 1996, entire document.	1-4, 12, 14-22
X	US 5,695,474 A (DAUGHERTY) 09 December 1997, entire document.	1-4, 12, 14-22
X	US 5,685,855 A (ERSKINE) 11 November 1997, entire document.	1-4, 12, 14-22
A	US 5,704,914 A (STOCKING et al) 06 January 1998, entire document.	1-5, 12-22
A	US 5,579,780 A (ZADINI et al) 03 December 1996, entire document.	6-11

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	* T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
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* O* document referring to an oral disclosure, use, exhibition or other means	
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Date of the actual completion of the international search

11 AUGUST 1999

Date of mailing of the international search report

02 SEP 1999

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